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09/914,340	02/19/2002	Hidekazu Shodai	YAMZ 2 00009	3665

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FAY SHARPE LLP
1228 Euclid Avenue, 5th Floor
The Halle Building
Cleveland, OH 44115

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/914,340	SHODAI ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8,10 and 12-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8,10 and 12-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 1, 7, 12-17, 19-24, 27-30 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. GB 2151201 A, in view of Monte US 5,578,336 and Brox US 4,780,316.

Ebert teaches a chewable soft gelatin capsule comprising confectionary fill material (abstract; and page 2, lines 40-47). The filled capsule is dried over a length of time until the desired chewing characteristics are attained (abstract; page 2, last paragraph; and examples). The capsule shell comprises gelatin, and plasticizer such as glycerin or sorbitol (page 1, last paragraph through page 2, paragraphs 1-5). The shell further comprises flavoring agent, and taste modifier (page 2, lines 33-35).

Ebert does not explicitly teach the claimed confectionary fill material.

Monte teaches a confectionary composition useful for the delivery of active agents, the composition comprising chocolate candy consisting mainly of roasted cacao beans, cacao butter, and sugar (abstract; column 5, lines 66 through column 6, lines 1-9; and example 29). Monte further teaches active agents include vitamins, enzymes, phytochemicals, and alimentary vegetable compositions are incorporated in the confection core (column 5, lines 30-35; and example 29). Thus, it would have been obvious to one of ordinary skill in the art to modify the chewable soft capsule of Ebert to include the confectionary composition of Monte to obtain the claimed invention, because Monte teaches using chewable confectionary composition as a carrier for drugs, because Monte teaches chewable confectionary such as chocolate candy is known in

pharmaceutical art, and because Ebert teaches the use of confectionary composition as a fill material suitable for the delivery of active agents.

It is noted that Ebert does not expressly teach the claimed drying temperature. However, absent of evidence to the contrary, the burden is shifted to applicant to show that Ebert does not dry the capsule under the claimed temperature. This is because Ebert teaches drying the soft gelatin capsule to obtain characteristics. It is noted that Ebert teaches an improved chewable soft gelatin capsule having the properties desired by the applicant, *e.g.*, normal chewing consistency over an extended period of time (page 1, lines 35-37), and avoidance of unpleasant taste (page 1, 2nd paragraph). However, to be more specific, Brox is cited for the teaching of storing (aging) soft gelatin capsule under temperature of 20°C, 30°C, and 40°C for one month to obtain a chewable capsule having suitable hardness (abstract; and column 5, lines 15-20). Therefore, it would have been obvious to one of ordinary skill in the art to age the soft capsule of Ebert at 30°C and 40°C in view of the teaching of Brox, because Brox teaches that it is well known to store soft gelatin capsule under such temperature to achieve suitable capsule shell hardness, and because Ebert teaches the desirability to obtain soft gelatin capsule having improved characteristics.

Claims 1, 4-7, 12, 15-17, 19-30 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. GB 2151201 A, in view of Cavanak US 5,639,724 and Brox US 4,780,316.

Ebert and Brox are relied upon for the reason stated above. Ebert does not explicitly teach the claimed filling material.

Cavanak teaches a confectionary composition comprising vegetable fats, and a drug such as cyclosporin (abstract; column 13, lines 7-26; and example 5). Vegetable fats include cacao fat, cacao butter, conventional chocolate bases, couverture chocolate, and mixtures thereof (ID). Example 5 discloses the claimed percent amounts of chocolate in the composition. Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule of Ebert to include the chocolate-cyclosporin candy in view of the teaching of Cavanak, because Cavanak teaches incorporating drug into chocolate base is known in pharmaceutical art, because Cavanak teaches a chocolate candy comprising cyclosporin to achieve acceptable taste (column 3, lines 41-45), and because Ebert teaches the use of confectionary as a fill material suitable for the delivery of a wide variety of drugs.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. GB 2151201 A, in view of Monte US 5,578,336 or Cavanak US 5,639,724, and Nishizawa et al. US 4,463,024.

Ebert in view of Monte or Cavanak are relied upon for the reasons stated above. Monte and Cavanak do not teach bitter chocolate.

Nishizawa teaches a flavoring composition comprising chocolate including bitter chocolate (example 18). Thus, it would have been obvious to one of ordinary skill in the art to include bitter chocolate to the chocolate composition of Monte or Cavanak to

obtain the in view of the teaching of Nishizawa, because Nishizawa teaches using bitter chocolate from cacao bean to obtain a superior flavoring composition, because Monte and Cavanak teaches the use of chocolate including cacao bean.

Claims 1, 4-7, 12, 15-17, 19, 20, 22, 24-30 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lech US 6,027,746, in view of Cavanak US 5,639,724.

Lech teaches a chewable soft gelatin capsule comprising a solid or liquid fill material (abstract; and column 2, lines 48-50). The fill material comprises flavors, sweeteners, and other food-grade excipient including oils and fats fillers (column 3, lines 1-4; and column 4, lines 66 through column 5, lines 1-17). Lech further teaches the filled capsule is stored at temperature 30°C, 40°C and 50°C for an extended period of time (aging) (column 7, lines 28-30).

Lech does not expressly teach the claimed fill material.

Cavanak teaches a confectionary composition comprising vegetable fats, and a drug such as cyclosporin (abstract; column 13, lines 7-26; and example 5). Vegetable fats include cacao fat, cacao butter, conventional chocolate bases, couverture chocolate, and mixtures thereof (ID). Example 5 discloses the claimed percent amounts of chocolate in the composition. Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule of Lech to include the chocolate-cyclosporin candy in view of the teaching of Cavanak, because Cavanak teaches it is well known in pharmaceutical art to use vegetable fat including chocolate base as a fill material for

oral dosage form, (column 3, lines 41-45), and because Lech teaches the desirability to use fill materials comprise flavors, sweeteners, and fats to obtain a suitable oral dosage form.

Claims 8, 12-16 and 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lech US 6,027,746, in view of Cavanak US 5,639,724 and Katsuragi et al. US 5,756,543.

Lech and Cavanak are relied upon for the reason stated above. Lech does not teach fats include lard, coconut oil, or polyethylene glycol.

Katsuragi teaches a bitterness-relieving agent comprising fats including vegetable and animal fats such as coconut oil, lard, and the like, and combination there of (abstract; and column 4, lines 12-30). Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule fill of Lech to include coconut oil, lard, and polyethylene glycol as a fat in view of the teaching of Katsuragi, because Katsuragi teaches the use of these fats in a composition to mask the taste of bitter drugs, and because Lech teaches the desirability to use fat as a fill material to obtain a suitable chewable capsule in which the bitter taste of drug has been masked.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lech in view of Mehta US 5,084,278.

Lech is relied upon for the reason stated above. Lech does not explicitly teach the flavoring agent such as chocolate flavor.

Mehta teaches a chewable taste mask capsule comprising a fill composition containing sweetening agent, and flavoring agent includes chocolate flavor (column 9, lines 46 through column 10, lines 1-15). Thus, it would have been obvious for one of ordinary skill in the art to include chocolate flavor in the fill material of Lech, because Mehta teaches the use chocolate flavor in chewable dosage form is preferable, and because Lech teaches the desirability to include a wide variety of flavors useful to obtain a chewable dosage form.

It is noted that the cited references do not teach the claimed crystal type for the fill material. However, such property is necessitated by drying the fill under the same condition as claimed. Accordingly, the burden is shifted to applicant to show that the dried fill material taught in the cited prior arts does not exhibit the claimed property.

Response to Arguments

Applicant's arguments filed 09/23/09 have been fully considered but they are not persuasive.

Applicant argues that the issue between Applicants and the Examiner appears to be clear. The Examiner's reasoning has relied on storage for extended periods of time as disclosing the aging step of the present claims. Applicants amended the claims to recite drying for a period of 5 to 64 hours. On page 8 of the Response to Arguments, the Examiner noted that Brox taught a storage condition at zero month. The Examiner also shifted the burden to Applicants to show that Lech's disclosure of "extended periods" indeed indicated a minimum storage period of one month. With regards to

Brox, the Examiner's reasoning relied on the time of storage to correspond to the aging time. Applicants submit that Brox's storage condition of zero months is equivalent to no drying/aging at all, i.e. a time of zero hours, which is outside the claimed floor of 5 hours. The Examiner's new reasoning is now below the claimed range of 5 to 64 hours. Thus, a storage time of zero hours will not render the present claims obvious. In addition, please note that Brox's examples require a starting reference point, i.e. zero months, to measure changes in properties over time. It would be unreasonable for the Examiner to equate zero months to any sort of aging.

However, in response to applicant's arguments that "*Brox's storage condition of zero months is equivalent to no drying/aging at all, i.e. a time of zero hours, which is outside the claimed floor of 5 hours. The Examiner's new reasoning is now below the claimed range of 5 to 64 hours. Thus, a storage time of zero hours will not render the present claims obvious*", it is of note that Brox does not disclose zero hour as alleged by the applicant. Zero month includes any time under a month, which could be hours or days. Further, applicant's attention is called to the teachings in Brox for storing (aging) soft gelatin capsule under temperature of 20°C, 30°C and 40°C for one month to obtain a chewable capsule having suitable hardness (abstract; and column 5, lines 15-20). It is noted that one month includes the time range required by the applicant. It is also noted that there is no particular upper limit for aging time since the effect of the aging time is saturated beyond a predetermined time. See present specification at page 21, lines 1-3. Accordingly, the drying condition taught by Brox is not outside of the claimed range of 5 to 64 hours.

Applicant rejects the assertion that it is Applicants' burden to prove the meaning of Lech's ambiguous phrase. Rather, it is the Examiner's burden to show that "extended periods" refers to a time period that renders obvious the claimed drying / aging time of 5-64 hours, as claimed. In addition, Applicants did not state that Lech itself indicated a minimum storage period of one month. Lech does not teach any minimum storage period. In addition, all that Lech states is that the capsules were stable, and that stability is with relation to the drug, not the actual properties of the capsule. There is no discussion of the ingestion properties of the capsules at all.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Lech is cited in view of Brox for the teaching of the drying parameters.

Applicant argues that U.S. Patent No. 6,071,523 to Mehta, previously cited by the Examiner, provides a reasonable basis for construing the "extended periods" of Lech to be longer than the claimed 64 hours. In column 2, lines 27-33, Metha states that three months storage at a temperature of at least about 40°C at 75% humidity extrapolates to two years shelf-life stability at room temperature under assumptions accepted by the U.S. Food and Drug Administration. Both Lech and Mehta are directed towards pharmaceutical compositions, so would reasonably have the same stability requirements and the same need to test for shelf-life. Lech tests at 30°C, 40°C, and

50°C, which reasonably surround the 40°C test described by Mehta. Although Lech does not state his humidity, Applicants submit that Mehta provides a basis for reasonably assuming that Lech's "extended periods" refers to a time period longer than the claimed 64 hours.

However, applicant's argument with respect to the time period longer than the claimed 64 hours is not persuasive for the following reasons: 1) although the "extended periods" in Lech might by longer than 64 hours as claimed, Lech does refer to a time period that falls within the claimed range, which is the time under 64 hours; and 2) as discussed above, it appears that there is no particular upper limit to the aging time as the effect of the aging time is saturated beyond a predetermined time (present specification, page 21, lines 1-3; and Fig. 3).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615